REPORT DOCUMENTATION PAGE	Form Approved OMB No. 0704-0188

1. AGENCY USE ONLY *(Leave blank)*	2. REPORT DATE	3. REPORT TYPE AND DATES COVERED
	7.May.99	THESIS

4. TITLE AND SUBTITLE
ADHERENCE TO THE OTITIS MEDIA WITH EFFUSION CLINICAL PRACTICE GUIDELINE BY PROVIDERS IN A UNITED STATES AIR FORCE MEDICAL TREATMENT FACILITY

5. FUNDING NUMBERS

6. AUTHOR(S)
MAJ PENGILLY PAULA L

7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)
UNIFORMED SERVICES UNIV OF HEALTH SCIENC

8. PERFORMING ORGANIZATION REPORT NUMBER

9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)
THE DEPARTMENT OF THE AIR FORCE
AFIT/CIA, BLDG 125
2950 P STREET
WPAFB OH 45433

10. SPONSORING/MONITORING AGENCY REPORT NUMBER
FY99-99

11. SUPPLEMENTARY NOTES

12a. DISTRIBUTION AVAILABILITY STATEMENT
Unlimited distribution
In Accordance With AFI 35-205/AFIT Sup 1

12b. DISTRIBUTION CODE

13. ABSTRACT *(Maximum 200 words)*

14. SUBJECT TERMS	15. NUMBER OF PAGES
	51
	16. PRICE CODE

17. SECURITY CLASSIFICATION OF REPORT	18. SECURITY CLASSIFICATION OF THIS PAGE	19. SECURITY CLASSIFICATION OF ABSTRACT	20. LIMITATION OF ABSTRACT

ADHERENCE TO THE OTITIS MEDIA WITH EFFUSION CLINICAL PRACTICE GUIDELINE BY PROVIDERS IN A UNITED STATES AIR FORCE MEDICAL TREATMENT FACILITY

Paula Lynn Pengilly

APPROVED:

C J Ledbetter — 12 Feb 99
Carol Ledbetter, PhD, RNc, CS, FNP — Date

Eugene Levine — 12 Feb 99
Eugene Levine, PhD — Date

L A Fritz — 12 Feb 99
Lorraine A. Fritz, MAJ, USA, NC — Date

APPROVED:

Fayez G. Abdellah — 4-26-99
F. G. Abdellah, Ed.D., ScD., RN, FAAN — Date
Dean

CURRICULUM VITAE

Name: Paula Lynn Pengilly

[redacted]

Degree and Date to be Conferred: Master of Science in Nursing (1999)

PII Redacted

[redacted]

[redacted]

[redacted]

Collegiate Institutions Attended:

Mount Marty College (Yankton, South Dakota)	1978-1982	BSN	May 1982	Major: Nursing
University of Colorado (Denver, Colorado)	1987-1989	MS	May 1989	Major: Nursing
USUHS (Bethesda, MD)	1997-1999	MSN	May 1999	Major: FNP

Professional Positions Held:

Current: Family Nurse Practitioner
96 Medical Operations Squadron
Eglin AFB, FL

DISCLAIMER STATEMENT

Department of Defense

"This work was supported by the Uniformed Services University of the Health Sciences Protocol No. T06166. The opinions or assertions contained herein are the private opinions of the author and are not to be construed as official or reflecting the views of the Department of Defense or the Uniformed Services University of the Health Sciences."

COPYRIGHT STATEMENT

The author hereby certifies that the use of any copyrighted material in the thesis entitled:

"ADHERENCE TO THE OTITIS MEDIA WITH EFFUSION CLINICAL PRACTICE GUIDELINE BY PROVIDERS IN A UNITED STATES AIR FORCE MEDICAL TREATMENT FACILITY"

beyond brief excerpts is with the permission of the copyright owner, and will save and hold harmless the Uniformed Services University of the Health Sciences from any damage which may arise from such copyright violations.

ABSTRACT

Clinical practice guidelines are developed to minimize variations in treatment patterns while assisting healthcare providers in clinical decision making. The United States Agency for Health Care Policy and Research published the Otitis Media with Effusion (OME) in Young Children Clinical Practice Guideline Number 12 widely disseminated by 1996. The guideline provides information on diagnostic criteria, hearing evaluations, environmental risk factors, therapeutic interventions, and a treatment algorithm. Initial treatment for OME does not require antibiotic therapy lessening microbial drug resistance. Little documentation exists reporting the application of this guideline. This study used a descriptive quantitative design to examine adherence to this guideline by healthcare providers in a United States Air Force Medical Treatment Facility. A total of 196 medical records of children diagnosed with otitis media were audited using a checklist developed from the treatment algorithm. Twenty-three of these children had OME. Using summary statistics, the audit showed antibiotics, decongestants, antihistamines, steroids and surgery were not used as per guideline recommendations. Areas of low compliance were use of the six-week follow-up interval, documentation of environmental risk factor control counseling, and documentation of the use of pneumatic otoscopy and/or tympanometry to evaluate the tympanic membrane for OME and acute otitis media.

Key Words: practice guidelines, otitis media, healthcare providers, microbial drug resistance, United States Agency for Health Care Policy and Research, risk factors

ADHERENCE TO THE OTITIS MEDIA WITH EFFUSION CLINICAL PRACTICE GUIDELINE BY PROVIDERS IN A UNITED STATES AIR FORCE MEDICAL TREATMENT FACILITY

by

PAULA L. PENGILLY, BSN, MS
MAJOR, USAF, NC

THESIS

Presented to the Graduate School of Nursing Faculty of

The Uniformed Services University of the Health Sciences

in Partial Fulfillment

of the Requirements

for the Degree of

MASTER OF SCIENCE DEGREE

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
May 1999

PREFACE

This research was conducted to provide information on the application of the Otitis Media with Effusion in Young Children Clinical Practice Guideline in a military treatment facility. It was designed to encourage the evaluation of the use of and clinical outcomes of guidelines available for practice today.

DEDICATION

Many people made this thesis a reality. Their support and encouragement helped me stay focused in completing the thesis as well as reminding me there is life besides school. I especially thank my husband, Dan, and my three daughters, Teresa, Molly, and Julie who continued to give me love and laughter at times when I was most stressed. Without my family's total support I would not have been able to complete school.

TABLE OF CONTENTS

LIST OF TABLES

LIST OF FIGURES

CHAPTER ONE - INTRODUCTION

Background

In the United States, "office visits for otitis media increased by 150 percent between 1975 and 1990, to 24.5 million (annually), with children under age 15 accounting for 81 percent of the visits" (Stool et al., 1994a, p. iii). In addition, children under age two had not only the highest rate of visits for otitis media, they also had the greatest increase in number of visits between 1975 and 1990: 224 percent. Of significance, is the increase in attendance in group daycare facilities by young children during this same timeframe. Stool et al. estimated direct and indirect medical management costs (clinic visits, medications, and parents' time lost from work) at $406 per patient visit and surgical management costs (myringotomy with insertion of tympanostomy tubes) at $2,174 per patient episode. Multiplying these costs by the number of visits results in a billion-dollar healthcare expenditure. Gates (1996) estimated the costs to be about five billion dollars annually. Cost is not the only factor important in the management of otitis media with effusion (OME). Accurate diagnosis, along with safe and effective quality patient care, is the utmost concern.

Acute otitis media (AOM) is inflammation of the middle ear with signs or symptoms of middle ear infection whereas OME is fluid in the middle ear without signs or symptoms of infection. Otitis media with effusion after therapy for AOM is expected (and may last several weeks to several months) and does not require retreatment (Dowell, Marcy, Philips, Gerber, & Schwartz,1998a). Treatments for OME include observation, antibiotics, and the surgical placement of tympanostomy tubes. With the variation in treatments, particularly antibiotic use, concern has been voiced about antibiotic side

effects, as well as their overuse and the potential development of resistant organisms (Shapiro & Bluestone, 1995). Another concern is the child who is inappropriately diagnosed and managed. OME can produce transient mild to moderate conductive hearing impairment but it is not known how long this impairment is required before permanent hearing loss or delays in speech or language occur.

Due to the concerns regarding the prevalence of OME, widespread variation of treatment patterns, debate about the appropriateness and timing of common treatments, and costs of OME, the Agency for Health Care Policy and Research (AHCPR), in 1991, awarded a contract to develop a clinical practice guideline on the diagnosis, treatment, and management of OME in young children. The product of this endeavor is Otitis Media with Effusion in Young Children: Clinical Practice Guideline, Number 12 (Stool et al., 1994a). Hereafter it will be referred to as the OME guideline. This practical guideline provides information on diagnostic criteria, hearing evaluations, environmental risk factors, therapeutic interventions, along with a treatment algorithm. Therapeutic interventions include pharmaceutical and surgical therapies. The OME guideline pertains only to the management of OME in children ages "one through three years with no craniofacial or neurologic abnormalities or sensory deficits, otherwise healthy except for otitis media with effusion" (Stool et al., 1994a, p. 4).

The treatment algorithm within the OME guideline (Stool et al., 1994a) provides recommendations and options for the primary care provider (medical doctors and midlevel providers such as nurse practitioners and physician assistants) to consider in the treatment of OME. When AOM is initially diagnosed, appropriate antibiotic therapy is initiated and the child is scheduled for a follow-up appointment (six week interval is

recommended) to evaluate the effect of the therapy. At this first follow-up appointment for AOM if OME is diagnosed the provider can choose to just observe the child or to prescribe antibiotics. The OME guideline suggests a follow-up interval of six weeks because no evidence regarding optimal visit intervals was found during its development.

The healthcare literature contains very few studies specifically on follow-up intervals for AOM or OME but discussions regarding intervals can be found in studies looking at the efficacy of various antibiotics. Intervals in these studies varied from 10 days to eight weeks (Stool et al., 1994a). Berman and Chan (1997) recommend that follow-up visits for children who are asymptomatic after treatment for AOM should be between three and six weeks. More importantly, these and other studies (Paap, 1996; Poehlman, 1996) consistently state that OME in the majority of cases that do not receive antibiotics on follow-up will resolve in the same time period as those where antibiotics are used. Follow-up intervals of less than six weeks may invite more frequent use of antibiotics with an increased risk of side effects, drug resistant organisms, and costs for both the consumer and health care agency.

Clinical practice guidelines are becoming more numerous and generally more acceptable by providers as evidenced in the literature. Sebring and Gerrerias (1996) stated in a 1993 survey that more than 31% of medical groups had formal treatment protocols, and more than two-thirds of the remainder were planning to implement them during the next two years. Eighty-five percent of the groups responding reported the guidelines are making an impact. The guidelines were used to help identify areas for quality improvement (85% of the responding groups), reduce variations in practice patterns (80%), and improve patient outcomes (45%). Sebring and Gerrerias stress the

need to conduct research on the extent to which the otitis media guideline is being used. Gray (1997), in his book on evidence-based healthcare, states that outcomes in terms of clinical behavior as measured by simple systematic checks on progress should be planned from the start of a new project. Berg (1996) stated "the current environment of wide practice variation, little information on outcomes, and disregard for the costs of care is not sustainable, and no other single strategy (clinical practice guideline) so squarely addresses these problems" (p. 366).

The OME guideline (Stool et al., 1994a) impacts medical providers in both the civilian and military medical environment. All providers have the medical, legal, and ethical obligation to treat all patients using the most current evidence-based medicine available. The OME guideline provides consistent strategies for all levels of providers in the appropriate diagnosis and management of otitis media with effusion in the young child. Homer, Grossman, and Rodman (1996) reviewed the use and impact of several pediatric clinical practice guidelines. They surveyed members of the Colorado Chapter of the American Academy of Pediatrics and American Academy of Family Physicians. These authors showed significant variation between the pediatricians and family practice providers in the management of persistent, asymptomatic OME. Homer, Grossman, and Rodman found:

> Family physicians were twice as likely to prescribe costly antibiotic therapy; at the six-week visit, 43% of the family physicians would use oral decongestants alone or in combination with other therapies as compared with 16% of the pediatricians, and family physicians were three times more likely than pediatricians to refer patients for ventilating tubes at the nine-week visit. (p. 434)

Purpose of the Study

Research conducted prior to 1994 did not offer consistent recommendations for the management of OME in young children to include follow-up intervals and treatments. The OME guideline (Stool et al., 1994a) was published and disseminated in 1994. More than 25,000 copies of the OME guideline and more than 150,000 copies of the physician's quick reference guides were requested by 1996 (Sebring & Gerrerias, 1996). Since development of the OME guideline, there has been no documentation in the literature on the usage of the protocol in the clinical practice environment, specifically the follow-up interval recommendation and medical management within the treatment algorithm. Thus, the purpose of this thesis was to examine the use of the AHCPR otitis media with effusion in young children guideline by providers in a United States Air Force (USAF) medical treatment facility.

Research Questions

Based on the review of the literature and the purpose of the study, the following research questions related to the adherence to the AHCPR otitis media with effusion clinical practice guideline were formulated.

1. What is the adherence to the OME clinical practice guideline on follow-up intervals by providers in an USAF clinic?
2. Are antibiotics ordered more frequently for OME if the patient is seen earlier than the recommended interval of six weeks?
3. Are pneumatic otoscopes or tympanometers used to diagnose OME?
4. Have environmental risk factors been documented?
5. Are decongestants or antihistamines being used in the treatment of OME when no other documented reason for their use is recorded?

6. Are steroids being used in the treatment of OME?

7. Is surgery being used in the treatment of OME?

Conceptual Framework

The art and practice of medicine has been evolving over the years with new technologies that have led to the development of complex life support equipment and drugs such as antibiotics and vaccines, to name a few. Along with this technology have been research and documentation of which therapies work and which do not for many clinical scenarios. Unfortunately, most of these studies vary in how they were conducted making it difficult to determine which therapies are best for the patients with similar illnesses. To aid in this dilemma, clinical practice guidelines are being developed through rigorous evidence-based methods by the Agency for Health Care Policy and Research. The Institute of Medicine defines guidelines as "systematically developed statements to assist practitioner and patient decisions about appropriate health care for specific clinical circumstances" (Homer, Grossman, & Rodman, 1996, p.431). Guidelines are used as a mechanism to assess and improve quality of care as well as a stimulus for conducting clinical research to determine whether they will change practices or improve patient outcomes.

The conceptual framework used in the development of this research study is the treatment algorithm (Appendix A) contained within the OME guideline (Stool et al., 1994a). The American Academy of Pediatrics developed this guideline under contract with the AHCPR. In order for the OME guideline to be more effective, and to encourage support of its use, a multidisciplinary committee with members from the American Academy of Family Physicians and the American Academy of Otolaryngology—Head and Neck Surgery, were included in the 19-member panel that met and reviewed more than 3,500 citations. The panel developed a final guideline that made 21 statements (recommendations, options, and no recommendations) regarding the management of

OME in young children (Berg, 1996). Each of these statements is discussed in detail as to how and why the panel came to these decisions based on available research or lack thereof. In addition, more than 100 peer reviewers were selected to critically review the guideline prior to its completion (Bluestone & Klein, 1995).

Conceptual frameworks are "a set of highly abstract, related constructs that broadly explains phenomena of interest, expresses assumptions, and reflects a philosophical stance" (Burns & Grove, 1997, p. 145). The OME guideline (Stool et al., 1994a) meets the requirements of this definition. It contains evidence-based statements on diagnosis, hearing evaluations, environmental risk factors, therapeutic interventions, and a treatment algorithm to relate these constructs.

The treatment algorithm is in a decision tree format that guides a provider in the management of OME in young children. This algorithm (Appendix A) was developed specifically for young children ages "one through three years with no craniofacial or neurologic abnormalities or sensory deficits, otherwise healthy except for otitis media with effusion" (Stool et al., 1994a, p. 4). It consists of 18 steps that include treatment options and recommendations for the management of OME based on pneumatic otoscopy and possibly tympanometry to confirm the diagnosis. Once OME is initially diagnosed after an episode of AOM (this begins the OME treatment algorithm), the provider has the option to observe the child and prescribe no antibiotics, or prescribe antibiotic therapy. Risk factor control counseling must be initiated at this point in the algorithm. The next step in the algorithm asks whether the patient still has OME six weeks after the initial diagnosis of OME by pneumatic otoscopy with optional confirmation by tympanometry. Again, if OME is diagnosed, the provider can choose to just observe the child, or treat with antibiotics. Risk factor control counseling for OME and the option for hearing evaluation must be addressed at this point. The interval recommended between follow-up appointments for OME is six weeks. The algorithm then continues on with possible

considerations for surgical involvement if medical therapy fails. Surgical management will not be addressed in this study.

Conceptual and Operational Definitions

Acute otitis media (AOM). Fluid in the middle ear accompanied by signs or symptoms of ear infection and inflammation (bulging eardrum usually accompanied by pain; or perforated eardrum, often with drainage of purulent material) as measured by otoscopy (Stool et al., 1994a). Operationally measured by the documentation of AOM in the medical record.

Otitis media with effusion (OME). Fluid in the middle ear without signs or symptoms of acute ear infection as measured by pneumatic otoscopy and possibly tympanometry to confirm the diagnosis (Stool et al., 1994a). OME is also referred to as serous or secretory otitis media (SOM), within the literature. Operationally measured by the documentation of OME or SOM in the medical record.

Otoscopy. Visualization of the tympanic membrane (also known as the eardrum) as measured by an otoscope. Operationally measured by the documentation of the condition of the tympanic membrane in the medical record.

Pneumatic otoscopy. Visualization of the tympanic membrane combined with a test of membrane mobility as measured by a pneumatic otoscope. Operationally measured by the documentation of the mobility of the tympanic membrane in the medical record.

Tympanometry. An indirect measure of tympanic membrane compliance and an estimate of middle ear pressure as measured by a tympanogram. Operationally measured by the documentation of the results of a tympanogram in the medical record.

Clinical practice guideline. "Guidelines are systematically developed statements to assist provider and patient decisions about appropriate health care for specific clinical conditions" (Stool et al., 1994a, p. ii).

Adherence. "To follow closely or to carry out without deviation" (American Heritage Dictionary, 1985, p. 79). Operationally measured by the documentation of how many days deviation from the clinical practice guideline recommendation of six weeks (42 days) as measured by the difference in number of days between the initial visit for AOM and the follow-up visit recommended by the provider, and the actual follow-up date recorded in the medical record as well as the interval between the initial diagnosis of OME and the first follow-up appointment for OME.

Follow-up interval. The time, in number of days, between the initial appointment dates diagnosing AOM and OME and the appointment date that assessed the effectiveness of the treatment provided.

Provider. Any licensed healthcare practitioner who is qualified to diagnosis and treat otitis media. Operationally measured by the documentation of the different provider's credentials in the medical record, or as recorded in the medical credentials office if missing from the record.

Different provider types. The various types of credentialled healthcare providers within the clinic who are qualified to diagnose and treat otitis media such as a physician (MD), pediatric nurse practitioner (PNP), family nurse practitioner (FNP), or physician assistant (PA).

Environmental risk factors. Factors in the child's surroundings that can be associated with OME. Factors include infant feeding practices, passive smoking, and group child-care facility attendance. Operationally measured by the documentation of bottle-feeding, passive smoking, and group child-care facility attendance in the medical record.

Documented. Information written in the medical record.

No other documented reason. This is operationally defined as the absence of documentation in the medical record supporting the need for antihistamines or decongestants during the treatment of OME such as rhinitis and nasal congestion.

Antibiotics. A pharmaceutical preparation that kills bacteria causing infection (Stool et al., 1994a, p. 85). Operationally measured as the documentation of its use in the medical record.

Decongestant. "An agent that reduces congestion or swelling" (Dorland's Illustrated Medical Dictionary, 1974, p. 412). Operationally measured as the documentation of its use in the medical record.

Antihistamine. "A drug that counteracts the action of histamine" (Dorland's Illustrated Medical Dictionary, 1974, p. 109). Operationally measured as the documentation of its use in the medical record.

Steroid. "A pharmaceutical preparation of adrenocorticosteroid hormone" (Stool et al., 1994a, p. 86). Operationally measured as the documentation of its us in the medical record.

Surgery. Surgical intervention such as myringotomy with or without tube insertion, tonsillectomy, or adenoidectomy for the treatment of OME. Operationally measured as documentation in the medical record of its recommendation or use.

Assumptions and Limitations

Assumptions are "statements taken for granted or considered true, even though they have not been scientifically tested" (Burns & Grove, 1997, p. 774). The majority of the assumptions in this thesis evolve around the technical and critical thinking skills of the healthcare providers. The following assumptions have been identified in the development of this thesis.

1. The provider has correctly diagnosed OME.
2. The provider is qualified in the use of the otoscope and pneumatic otoscopy.
3. The provider or technician is qualified in the use of the tympanometer.
4. The provider is qualified in the interpretation of the tympanogram.
5. The provider is aware of environmental risk factors for OME.
6. The provider is aware of the 1994 clinical guideline on OME.

"Limitations are restrictions in a study that may decrease the generalizability of the findings" (Burns & Grove, 1997, p. 49). Limitations for this thesis surround the issue of accurate documentation in the medical records, the single setting, and parental compliance. The medical record is "often incomplete in what it documents, frequently omitting significant elements of technical care" (Donabedian, 1988, p.1747). The limitations for this thesis include:

1. The results apply only to the clinics where the data were collected.
2. This study is limited to children age 12 to 48 months who are otherwise healthy except for OME.
3. This study is limited by the compliance of parents to schedule and keep follow-up appointments as recommended by the provider.
4. This study is dependent on the accurate and thorough documentation of data in the medical record.
5. No algorithm will apply to all clinical cases.

CHAPTER II – REVIEW OF THE LITERATURE

Prior research studies have highlighted several concepts relevant to the management of OME in young children (Stool et al., 1994a). These concepts were treatment variations, follow-up intervals, clinical practice guidelines, antibiotic resistance, and risk factors for OME. The following is a review of the literature regarding these concepts.

Treatment Variations

Stool et al. (1994a), in a meta-analysis of 10 studies, looked at the variety of antibiotic agents chosen plus steroid, decongestant, and antihistamine use. The variety of methods used to diagnose OME and to assess the effectiveness of the medications chosen to treat OME were also examined. A total of seven different antibiotics had been used to treat OME in the studies reviewed. There was no consistency in how OME was diagnosed nor in how treatment effectiveness was measured. OME was diagnosed using tympanometry, otoscopy, hearing evaluation, or a combination of these methods. Missing in this study is information on the use of pneumatic otoscopy and the overall cost-effectiveness of various antibiotic therapies in terms of how they may decrease the need for more expensive interventions such as surgery and hearing evaluations.

The OME guideline (Stool et al., 1994a) clearly states the use of steroid medications is not recommended for the treatment of OME in a child of any age. Although this statement is based on limited scientific evidence available on the efficacy of steroids in the treatment of OME, the panel's majority opinion supported it. The research studies reviewed by the panel utilized three different comparisons: steroid treatment alone versus placebo, steroid plus antibiotics versus antibiotics alone, and

steroid plus antibiotics versus placebo (Stool et al.,1994a). The results of this meta-analysis concluded that the benefit of early clearance of OME using steroids was short lived and was not statistically significant. Many of these studies had small sample sizes. The meta-analysis did show a positive trend of these statistics reaching statistical significance in the steroid plus antibiotic group but not significant enough to advocate the use of steroids at this time.

Antihistamines and decongestants also do not aid in the resolution of OME and thus are not recommended in the treatment of OME for children of any age (Stool et al., 1994a). A meta-analysis of four studies reviewed did not show statistical significance in the clearance of OME with the use of antihistamines and decongestants. In addition, these drugs do have adverse effects including insomnia, drowsiness, behavior changes, changes in blood pressure, and seizures.

Surgical intervention is often a choice for persistent OME but is not recommended in the early course of OME. Surgical intervention includes myringotomy with or without tympanostomy tubes, tonsillectomy and adenoidectomy. This recommendation was based on strong evidence regarding the natural course of AOM where OME is a common finding following AOM and that the majority of OME cases will spontaneously resolve (Stool et al., 1994a). Dowell, Schwartz, and Phillips (1998) concur that 70% of children will have fluid at two weeks, 50% at one month, 20% at two months, and 10% at three months.

Follow-up Intervals

Stool et al. (1994a) also conducted a meta-analysis of various treatment regimens for OME and found that follow-up visits ranged from ten days to eight weeks with no

clear evidence for any specific interval. Thus, the panel, based on the literature and panel consensus, set the guideline recommendation for follow-up visits at six weeks.

Berman and Chan (1997) state the optimal timing depends on the child's response to therapy and risk factors for treatment failure (less than 15 months of age, prior history of recurrent otitis media, or a history of antibiotic treatment of acute otitis media within the prior month). Overall, they recommend that follow-up visits should be scheduled three to six weeks following the initial appointment for asymptomatic children, which nears congruence with the 1994 Stool et al. study. Symptomatic children need to be evaluated sooner. Other studies reviewed by Berman and Chan (1997) confirm the desirability for this interval because of the lack of support showing antibiotics significantly resolve OME more quickly. Table 1 summarizes follow-up intervals found in several major pediatric medical textbooks.

Table 1

Recommended Follow-Up Intervals for Acute Otitis Media (AOM) and Otitis Media with Effusion (OME)

AOM Interval	OME Interval	Author
2 weeks	6 weeks	Behrman, Kliegman, and Arvin (1996)
2-3 weeks	None stated	Haekelman, Friedman, Nelson, Seidel, and Weitzman (1997)
4 weeks	None stated	Burg, Ingelfinger, Wald, and Polin (1996)
3-6 weeks	3-4 weeks	Berman (1996)
8 weeks	None stated	Dershewitz (1988)

Mandel, Casselbrant, Rockette, Bluestone, and Kurs-Lasky (1995) conducted a study among 267 children with AOM randomly assigned to three treatment groups: amoxicillin for 20 days, amoxicillin for 10 days plus amoxicillin clavulanate on days 11-20, and amoxicillin for 10 days and placebo for the next 10 days. Medications were dispensed in a double-blind manner. The children were reexamined at days 10, 20, 30, 60, and 90 after initial tympanocentesis at entry into the study. The researchers stated:

> More children were effusion free by the day 20 visit if given antimicrobial treatment for 20 days rather than for 10 days, but this advantage was present for only a short time; by the end of the 90 day study period, the treatment groups were comparable with regard to effusion status. (p. 5)

Antimicrobial Resistance

Cohen (1997), McCracken (1998), and Dowell, Marcy, Phillips, Gerber and Schwartz (1998b) state that the growth of antimicrobial resistant strains of bacteria is a growing national and worldwide public health concern. Also, there are now organisms that are resistant to multiple drugs. These organisms have emerged with the widespread use of antimicrobials in the outpatient and inpatient setting, whether appropriate or inappropriate. "For example, more than five cross-sectional studies have documented that the likelihood of culturing a resistant strain of pneumococcus from the nasopharynx is increased if the patient recently completed a course of antibiotics" (p.163).

The emergence of antimicrobial resistance is being attributed to several causes. These include increasing populations of susceptible hosts, international travel and commerce, changes in technology and industry, microbial adaptation and change, and the breakdown of public health measures (Cohen, 1997). To combat these problems will

require enhanced surveillance, development of more and better vaccines, increased emphasis on infection control and hygienic practices, and prudent use of existing antimicrobial drugs.

According to the National Center for Health Statistics nearly three fourths of all outpatient antibiotics prescribed have been for otitis media, sinusitis, bronchitis, pharyngitis, or nonspecific upper respiratory tract infection with otitis media being the leading indication (Dowell et al., 1998b). If AOM and OME are not properly diagnosed, then unnecessary prescribing of antibiotics could occur contributing to antimicrobial resistance. Moser (1994) and Berman and Chan (1997) state that AOM is commonly over diagnosed due to physician and parental bias to treat a sick child with antibiotics, not removing enough cerumen to adequately see the tympanic membrane, and believing any red membrane with normal mobility is AOM. A goal to minimize antibiotic overuse would then be to correctly identify patients who would benefit from antibiotic therapy and those who would not benefit. "Conscientiously distinguishing acute otitis media (AOM) from otitis media with effusion (OME), and deferring antibiotics for OME will accomplish this goal, and will avoid up to 8 million unnecessary courses of antibiotics annually" (Dowell et al., 1998a, p. 165-166). Paap (1996) also stresses the point of not overusing antibiotics as he identifies in the clinical practice guideline algorithm the option to use antibiotics versus only observation in the early phase of asymptomatic OME may lead to widespread indiscriminate use of antibiotics.

Risk Factors

Stool et al. (1994a) conducted a literature review during the development of the OME guideline and found several risk factors associated with OME. There is no research

that studied the strength of the link between each risk factor and OME. Also, no studies identified whether intervening to decrease environmental risk factors made any difference in the frequency or resolution of OME. Though the research link was weak, the panel strongly recommended parents should be encouraged to control environmental risk factors.

Risk factors identified by Stool et al. (1994a) included infant bottle-feeding, passive smoking, and attendance at group child-care facilities. Poehlman (1996) and Daly (1994) identified significant factors that increased the risk of otitis media with effusion to include male gender, white race, young age, and early onset of otitis media, day-care attendance, parental smoking, a family history of middle ear disease, and a family or personal history of allergy. Additional risk factors were taking a bottle in bed, bilateral otitis media, a prior history of OME, nasal obstruction, fall and winter seasons, and the number of siblings. The only protective factor was breast-feeding.

Identification of risk factors can easily be obtained by the provider by asking parents a few questions. Control of risk factors is not as easy because it requires parental cooperation and frequently a change in life style for one or both parents.

Clinical Practice Guidelines

"When the outcomes of an intervention are uncertain or variable, and/or when patients' preferences for those outcomes are uncertain or variable, practitioners must be given flexibility to tailor a policy to individual cases" (Eddy, 1990, p. 3077). To meet this need for flexibility, three types of practice policies are available: standards, guidelines, and options.

Standards are rigid and must be followed in all cases with rare exceptions. This is supported by Magit and Stool (1993) who state the consequences of a clinical intervention are well known for standards, and there is virtual unanimity among providers regarding the preferred approach to the clinical scenario.

Guidelines, on the other hand, are less rigid and should be followed in most cases. Clinical outcomes of important interventions are sufficiently known and supported by the majority of providers. Guidelines should be tailored on patient's needs, setting, and other factors (Eddy, 1990; Meritt, Palmer, Bergman, & Shiono, 1997). Pros and cons need to be discussed as well as indications, contraindications, drugs, and procedures of choice.

The third type of practice policies are options. Options provide the practitioner with the freedom to choose any intervention within the guideline that meets the patient's needs. With options, outcomes for interventions are desirable but the patient's preferences may not always be known. Whether a standard, guideline, or option, these practice policies are the result of economic pressures to achieve a baseline level of practice in clinical settings.

Clinical practice guidelines are written for specific clinical scenarios such as the OME guideline (Stool et al., 1994a) for young children. This guideline has its strengths and weaknesses that are clearly identified and listed in the guideline itself. Part of the strength of guidelines lie in their development.

The panel charged with the OME guideline (Stool et al., 1994a) development followed an explicit, evidence-based process. They conducted a quality literature review and each recommendation is annotated with a statement giving the level of the science and expert opinion that supports it (Berg, 1994). Bluestone and Klein (1995) reviewed

the OME guideline and reported several strengths such as parent education about treatment methods, environmental risk factors, provider education about the need for pneumatic otoscopy, and emphasizing that OME is self-limiting. They also commented that no algorithm will apply to all cases which is consistent with Eddy (1990) and Magit and Stool (1993).

"Practice parameters and guidelines have grown in use because of powerful interests—third-party payers, insurers, and health maintenance organizations, as well as hospital administrators bent on reducing variable costs of care and contracting for capitated care" (Meritt et al., 1997, p.100). These authors also point out that there is limited evidence that these guidelines have achieved the desired goals of reducing health costs, improving quality of care, and limiting malpractice liability, which is also supported by Berg (1996). Research is necessary to reevaluate the guidelines and ensure they are having the desired effect on clinical outcomes.

A survey of 555 pediatricians (300 responded) by Christakis and Rivara (1998) looked at their awareness of and attitudes about four clinical practice guidelines. The guidelines included the OME guideline, Practice Parameter for Hyperbilirubinemia in Healthy Term Newborns, Practice Guideline for the Management of Infants 0-36 months With Fever Without a Source, and the Guide to Clinical Preventive Services. Of those responding, 66% were aware of the hyperbilirubinemia guideline, 64% of the fever guideline, 50% of the OME guideline, and 16% of the preventive care guideline. Most pediatricians did not perceive the guidelines as very helpful. More recent graduates did find them helpful and said they were more likely to change their behavior because of them.

Summary

The review of the literature identifies various concepts related to the management of OME in young children. More importantly it identifies gaps where further research is needed to support the continued use of developed clinical practice guidelines. For example, whether the guidelines produce the clinical outcomes they were designed to achieve such as changing practice, reducing costs and improving the quality of care has not been researched. In addition, are various parts of guidelines followed more than others? And, the central question of this thesis, what is the adherence to the clinical practice guideline on OME in young children?

CHAPTER 3 – METHODS

Research Design and Procedures

This study used a descriptive quantitative design to measure the adherence to the OME guideline (Stool et al., 1994a). Data were gathered using a checklist (Appendix B) developed by the researcher using the OME guideline treatment algorithm. Data were collected retrospectively from chart reviews of documented medical care conducted during the peak season for acute otitis media. Data collection began in July 1998 and was completed in October 1998. The medical records were reviewed within the medical facility and returned to the medical record section upon completion of data collection. A total of 196 medical records were reviewed.

Sample

Children who received medical care during the peak season for AOM at an Air Force medical treatment facility and who met the established inclusion criteria were eligible to be in the study. Inclusion criteria were: (a) any child age 12 to 48 months with no craniofacial or neurological abnormalities or sensory deficits, otherwise healthy except for OME, (b) no documentation of prophylactic antibiotics for recurrent AOM, (c) documentation of fewer than three episodes of AOM in the past six months, and (d) no documentation of pneumatic tubes now or in the past. Stool et al. (1994b) defined an otherwise healthy child as one who has no evidence of craniofacial or neurological abnormalities (such as cleft palate, mental retardation, or swallowing dysfunction) or sensory deficits (such as decreased visual acuity or pre-existing hearing deficit).

Exclusion criteria were: (a) any child less than 12 months or more than 48 months old, (b) any child with craniofacial or neurological abnormalities or sensory deficits,

(c) any child who had experienced three or more episodes of AOM in the past six months, (d) any child with a history of pneumatic tubes, and (e) any child on prophylactic antibiotics.

Medical records included in the study came from a master list of 794 children seen for AOM between 1 October 1997 and 31 March 1998 in both the Family Practice and Pediatric Clinics. These were the only clinics routinely treating children under five years of age. Children eligible to be included in the study were identified through the International Classification of Diseases, Ninth Edition, Clinical Modification code 382.9 for otitis media (DHHS Publication No. 91-1260, 1991). Each name on the list was assigned a number. Potential subjects were initially selected using a Table of Random Digits. When it became apparent that many records were unavailable, selection was changed to a convenience sample in order to increase the sample size. Only medical records physically present at the time of screening for eligibility were included. Ineligible records were returned to the appropriate record section and removed from the master list. Other names were selected as replacements as needed. The first 196 eligible records physically present were included in this study. Each record was audited using the data collection tool in Appendix B. The 20 medical records used in the pilot study were included in the final data analysis because no major changes were made to the data collection checklist upon completion of the pilot study.

Measurement

A checklist was used to audit medical records to determine how closely health care providers follow the OME guideline (Stool et al., 1994a) through the first follow-up appointment for OME. The checklist was developed using the established treatment

algorithm (Appendix A) contained within the guideline. Steps in the algorithm were reviewed and documented on the checklist with each medical record reviewed, beginning with the initial appointment for AOM through the first follow-up appointment when OME was diagnosed.

The checklist collected demographic information on the age and gender of the patient plus the type of clinic where the child had been diagnosed with AOM and evaluated after treatment. Type of provider was determined for both visits: advanced practice nurse (PNP and FNP), physician assistant, or medical doctor.

Follow-up intervals were determined by collecting Julian dates for the initial date AOM was diagnosed, the follow-up date recommended by the provider, the actual date the patient was seen for their follow-up appointment for AOM, and the first follow-up appointment scheduled after the diagnosis of OME was established. The antibiotic ordered for the initial treatment of AOM was collected. The diagnosis made on the follow-up visit was recorded as AOM, OME, normal, or other. Whether pneumatic otoscopy or a tympanogram was used to assist in making the diagnosis during the follow-up exam was also recorded.

If OME was diagnosed, additional information, or lack there of, was recorded. This included: (a) whether antibiotics were prescribed or not, and if yes, which one, (b) whether risk factor control counseling was documented, (c) whether decongestants or antihistamines were ordered, and if so, reason documented, (d) whether steroids were ordered, and (e) whether surgery was recommended or performed. Risk factor control counseling also included whether bottle-feeding, passive smoking, or group childcare was discussed as risk factors for otitis media with effusion.

Validity and Reliability

The checklist was tested for content-related validity using a panel of two experts. The experts included a certified pediatric nurse practitioner with more than ten years of recent clinical experience and a certified family nurse practitioner with more than two years of recent clinical experience. The degree of validity reflects "the extent to which the method of measurement includes all the major elements relevant to the construct being measured" (Burns & Grove, 1997, p. 331). A content validity index of ≥ 0.8 was predicted and obtained. No item fell below the predicted index.

Once the validity of the checklist was assessed, the degree of reliability was tested through a pilot study of 20 eligible medical records. "Reliability represents the consistency of measure obtained" (Burns & Grove, 1997, p. 327). The intra-rater reliability method was used rather than the inter-rater reliability because only a sole researcher collected the data. A reliability of ≥ 0.8 was predicted and obtained for the checklist. During the pilot study, the medical records were audited twice by the sole researcher at two different times using the checklist. A time span of two weeks was used between the two audits. The number of agreements per checklist item determined the degree of reliability. A total of 36 checklist items (including the exclusion and inclusion data) were evaluated. Of the initial 20 records available at the first audit, only 16 were available two weeks later for the second audit. All 16 available were reviewed, and were in 100 percent agreement with the first audit. Coding methodology was deemed stable.

Protection of Human Rights

A copy of this proposal was submitted to and written approval obtained from the Institutional Review Board, Research Administration at the Uniformed Services

University of the Health Sciences prior to the initiation of the study (Appendix C). Once this approval was obtained, permission to conduct the study at a medium-large United States Air Force medical treatment facility was obtained in writing through their Internal Review Board, Medical Education and Training Flight. Copies of each of the IRB approvals were provided to the TRICARE Flight personnel who generated a list of potential patient medical records. Additional copies were provided to the officer in charge of the outpatient record sections and the personnel in charge of each of the clinic record sections before they would pull the actual medical records for the audit.

Steps were taken to maintain patient confidentiality and to protect the rights of the patients whose medical records were reviewed and the healthcare providers for those patients. Access to the master list containing names, social security numbers, and randomly assigned numbers was limited to the sole researcher. Medical records were obtained directly from each outpatient record section of the Pediatric Clinic and the Family Practice Clinic and returned immediately following the chart audit. Medical records were never removed from the clinic setting. Information from the medical records will remain confidential. Data from the medical record reviews were compiled as a whole. No attempt was made to associate research results with individual health care providers or their patients.

Data Analysis

Data analysis was completed using summary statistics (percents, means, and frequencies). Once the checklists were completed, data was entered into a computer and analyzed using the SPSS (Statistical Product and Service Solutions version for personal

computers) Software Program. A description of the clinics, provider types, range in age, and gender distribution of the sample was tabulated.

The actual follow-up intervals are described in terms of how much they differed (in number of days) from what the provider ordered and how they differed from the AHCPR guideline's recommended follow-up interval of six weeks (42 days).

The type of antibiotic ordered is displayed in a table showing the frequency and percent it was ordered by each clinic and provider type such as MD, PA, or advanced practice nurse (FNP and PNP). The frequency of each diagnosis made (AOM, OME, or normal) during the follow-up appointment is tabulated. The percent use of pneumatic otoscopy or tympanogram to support the diagnosis is also computed for each provider type as well as between clinics.

Frequencies and percentages of whether antibiotics were ordered for OME are tabulated. The frequency and percent of each provider type who ordered antibiotics, documented risk factor counseling, ordered decongestants or antihistamines and documented the reason for their use, and whether steroids or surgery were ordered are determined. The specific types of OME risk factors documented in the medical record and their frequencies are described in the text as well.

Summary

This study conducted a retrospective chart review using a descriptive design to measure adherence to the OME guideline for young children by medical providers. The pilot study determined the reliability of the checklist. Content-related validity was established. A total of 196 records were audited. Summary statistics are displayed in

various tables. Extreme care was taken to protect the confidentiality of the subjects, the providers, and the military medical treatment facility.

CHAPTER IV – ANALYSIS

Presentation, Analysis & Interpretation of Data

The purpose of this study was to examine the use of the OME guideline (Stool et al., 1994a) by providers in a United States Air Force medical treatment facility. This chapter presents a description of the sample, demographics, and documentation of the use of specific steps in the clinical guideline as well as the providers' or clinics' adherence to them. These steps included pneumatic otoscopy, risk factor counseling, use of antibiotics, decongestants, antihistamines, steroids, or surgical intervention in the OME management, and use of the recommended follow-up appointment interval of six weeks. A brief discussion of the population and sample will be presented first.

The total potential population consisted of 794 medical records (216 from the Family Practice Clinic, and 582 from the Pediatric Clinic) which included all the children aged 12 to 48 months who were seen for AOM between 1 October 1997 and 31 March 1998. Many of the requested records (54%) were not available due to record transfers, retirements, checked out for other appointments, or signed out by the patient's family or guardian. Of 269 records actually available for review, 196 met established eligibility criteria described under methodology. Sixty percent of the eligible records came from the Pediatric Clinic, and 40% from Family Practice.

Description of the Final Sample

The ages of the final sample of children ranged from 12 through 47 months with a mean of 24 months. Forty-seven percent of the sample were male, and fifty-two percent female.

Fifty-four percent of the initial diagnoses of AOM were made within the Pediatric Clinic, 39% in Family Practice Clinic, 4% in Primary Care and 3% in the Emergency Room. Medical doctors evaluated 66% of the children, advanced practice nurses 30%, and physician assistants 3%. One medical record was unsigned therefore the provider type could not be determined.

Each child diagnosed with AOM was prescribed an antibiotic. Amoxicillin was ordered as the drug of choice for AOM in 70% of cases followed by co-trimoxazole 16% (Table 2). Medical doctors used amoxicillin as their first choice in 72% of the cases (Table 3). Co-trimoxazole was next most frequent, 12%. Advanced practice nurses ordered amoxicillin 68% and co-trimoxazole 24% of the time for AOM. Physician assistants also used amoxicillin as their first choice, 66%. Medical doctors used amoxicillin+clavulanic acid, azithromycin, and ceftriaxone more frequently than the advanced practice nurses did. Table 4 provides the breakout of antibiotics ordered by clinic.

Amoxicillin was also the drug of choice for the initial treatment of AOM in the 23 children later diagnosed with OME. It was prescribed 65% of the time by all groups of providers. This was followed by co-trimoxazole and amoxicillin+clavulanic acid each at 13% and azithromycin at 9%.

Of the initial 196 children diagnosed and treated for AOM, 69% had a documented follow-up appointment to evaluate the treatment provided whereas 31% had no documented follow-up appointment in the medical record. During this follow-up appointment, a diagnosis of AOM, OME, or normal findings (AOM had resolved) was documented. AOM was diagnosed in 22%, OME in 17%, and normal findings in 61%. Of the 23 children diagnosed with OME, 13 were male and 10 female. Their ages ranged from 12 to 47 months with a mean of 24.

Fifty-six percent of the follow-up appointments for AOM were conducted in the Pediatric Clinic, 42% in the Family Practice Clinic, and 2% at other military medical treatment facilities in the local area. Medical doctors evaluated 77% of the children, and advanced practice nurses 23%. Though physician assistants were identified as diagnosing an initial AOM event, none were identified in the follow-up appointment.

Table 2

Antibiotic Ordered for Acute Otitis Media

	Frequency of Cases	
Antibiotic	#	%
Amoxicillin	137	70
Co-trimoxazole (Septra)	31	16
Amoxicillin+clavulanic acid (Augmentin)	12	6
Azithromycin (Zithromax)	7	3
Erythromycin+sulfisoxazole (Pediazole)	5	2
Ceftriaxone (Rocephin)	3	1.5
Vantin	1	0.5
Total	196	100.0

Table 3

Antibiotic Ordered for Acute Otitis Media by Provider Type

Antibiotic Ordered	Provider Type: Medical Doctor #	%	Nurse Practitioner #	%	Physician Assistant #	%	Totals #	%
Amoxicillin	93	72	40	68	4	66	137	70
Amoxicillin+clavulanic acid (Augmentin)	10	8	2	4	0	0	12	6
Azithromycin (Zithromax)	6	5	0	0	1	17	7	4
Ceftriaxone (Rocephin)	3	2	0	0	0	0	3	2
Erythromycin+sulfisoxazole (Pediazole)	3	2	2	2	0	0	5	3
Co-trimoxazole (Septra)	15	12	14	24	1	17	30	15
Vantin	0	0	1	2	0	0	1	1
Total	130	100	59	100	6	100	195	100

Table 4

Antibiotic Ordered for Acute Otitis Media by Clinic Where Initially Diagnosed

Antibiotic Ordered	Clinic Type by Case Frequency									
	Pediatric Clinic		Family Practice		Primary Care		Emergency Room		Total	
	#	%	#	%	#	%	#	%	#	%
Amoxicillin	71	67	58	75	5	63	3	50	137	69
Amoxicillin+ clavulanic acid	5	5	5	7	2	25	0	0	12	6
Azithromycin	1	1	4	5	1	12	1	16	7	3
Ceftriaxone	1	1	2	3	0	0	0	0	3	2
Erythromycin+ sulfisoxazole	3	3	1	1	0	0	1	16	4	3
Co-trimoxazole	23	22	7	9	0	0	1	16	31	16
Vantin	1	1	0	0	0	0	0	0	1	1
Total	105	100	77	100	8	100	6	100	196	100

Guideline Adherence

Pneumatic Otoscopy

Fifty-three percent of the records audited showed documentation of the use of the pneumatic otoscope and/or tympanogram during the examination of the child in the follow-up appointment. Forty-seven percent of the records did not have documentation of the use of the pneumatic otoscope or tympanogram. Their use is described for each type of clinic and provider in Tables 5 and 6. Seventy-five percent of the providers in the Family Practice Clinic documented use of the pneumatic otoscope compared to only 37% in the Pediatric Clinic. Medical doctors documented use of pneumatic otoscope more frequently at 60% than advanced practice nurses, 39%. Fifty-seven percent of the children with OME at the follow-up visit had pneumatic otoscopy documented in their medical records whereas 43% did not. When pneumatic otoscopy was not documented, comments such as "still has fluid", "bulging", and "serous otitis" were recorded under the examination of the ear for the patients with OME. Patients with resolved AOM had comments such as "TMs clear", "TM with good landmarks", and "normal" or "clear". Those with persistent AOM or recurrent AOM had comments such as "right purulent fluid level", "poor landmarks", or "bulging".

Risk Factors

Of the 23 patients diagnosed with OME, 48% had risk factor counseling documented, and 52% did not. Environmental risk factor control counseling is a requirement in the OME guideline (Stool et al., 1994a). Risk factor control counseling was further broken down into the three main risk factors: bottle-feeding, passive smoke, and group child-care. Of the 11 records with documented counseling, three identified passive smoking and four identified group child-care as risk factors for OME. No record identified that bottle-feeding was a risk factor for children with OME. Other risk factors documented, once each, were family history, male gender, and allergies. One record

Table 5

Pneumatic Otoscopy and/or Tympanogram Use by Clinic Where Follow-up for Acute Otitis Media Conducted

	Pneumatic Otoscopy and/or Tympanogram Use Frequency of Cases					
	Yes		No		Total	
Clinic Type	#	%	#	%	#	%
Pediatric	28	37	48	63	76	100
Family Practice	43	75	14	25	57	100
Military Other	1	33	2	67	3	100
Total	72	53	64	47	136	100

Table 6

Pneumatic Otoscopy and/or Tympanogram Use by Provider Type

	Pneumatic Otoscopy and/or Tympanogram Use Frequency of Cases					
	Yes		No		Total	
Provider Type	#	%	#	%	#	%
Medical Doctor	51	60	34	40	85	100
Nurse Practitioner	18	39	28	61	46	100
Physician Assistant	3	75	1	25	4	100
Medical Doctor	0	0	1	100	1	100
Total	72	53	64	47	136	100

stated a child had no identifiable risk factors. Two records stated children had risk factors but the provider failed to document specific ones.

Antibiotics for Treatment of OME

One out of 23 providers chose the option of antibiotics for the management of OME. The other approved option is observation only.

Decongestants and Antihistamines

Twenty-one of 23 providers chose not to prescribe decongestants and antihistamines as part of the therapy for OME, which is in compliance with the OME guideline (Stool et al., 1994a) recommendations. Two patients were prescribed one of these drugs. One of the records provided the required documentation to support the prescription, and the other did not.

Steroids and Surgical Intervention

Healthcare providers did not order steroids or refer for surgical intervention in the management of otitis media with effusion. This shows further compliance with the OME guideline (Stool et al., 1994a) in the management of otitis media with effusion in young children.

Follow-up Intervals

Three different follow-up time intervals were measured:
(a) number of days, between the diagnosis of AOM and the ordered follow-up appointment, (b) number of days ordered for the follow-up appointment once OME was diagnosed, and (c) number of days between the ordered follow-up appointment for AOM and the actual date the child was evaluated.

The results determined for the first interval between the acute event and the initial follow-up are found in Table 7. This interval ranged from 2 to 42 days. Thirty-five percent of providers ordered 14 days, 36% ordered 21 days, and 12% ordered 28 days accounting for 83% of all appointments. Only three records had appointments ordered for the guideline recommendation of 42 days (six weeks). Eighteen records did not have

any documentation ordering a follow-up appointment. Figure 1 depicts the actual follow-up intervals specifically for the children later diagnosed with OME, their age in months, and how these intervals varied from the guideline recommendation of 42 days (six weeks). Children seen earlier than 10 days were being followed for potential dehydration, high fevers, or unresolved or worsening symptoms.

Table 7

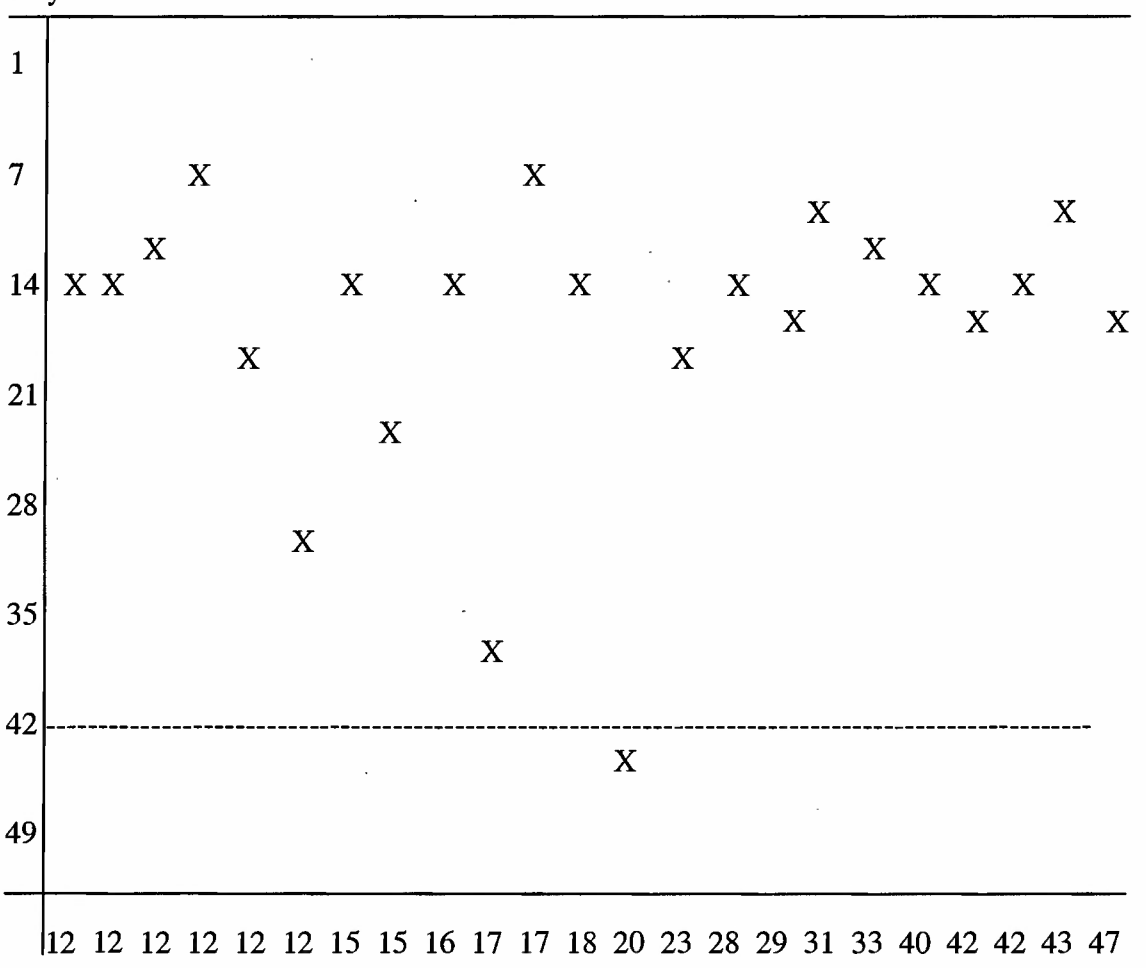
Follow-up Interval in Days Ordered for Acute Otitis Media

	Frequency of Cases		
Interval in Days	#	%	Cumulative %
2	1	*	0.5
5	1	*	1.0
7	4	2	3.0
10	6	3	6.0
14	69	35	41.0
21	71	36	77.0
28	23	12	89.0
42	3	2	91.0
No order	18	9	100.0
Total	196	100	100.0

* Less than 1%.

Figure 1

Acute Otitis Media Follow-up Intervals of 23 Children Diagnosed With Otitis Media with Effusion Compared with Guideline Recommendation of 42 Days



X = Actual follow-up interval, in days, for acute otitis media in children diagnosed with otitis media with effusion

--- = OME guideline interval recommendation of six weeks (42 days)

The second interval is the follow-up appointment ordered for the 23 OME cases. All patients diagnosed with OME, except one, were ordered follow-up appointments. The appointments ordered ranged from 14 to 42 days. Sixty-eight percent of the appointments were scheduled for 28 days. Twenty-three percent were ordered for 14 days, and 9% ordered for 21 and 42 days as the interval for evaluation of the otitis media with effusion.

Another interesting time interval was the difference between when the provider ordered the follow-up appointment for the AOM and the actual date the patient was evaluated. In twenty-five records there was no difference, thus 19% of the patients were seen on the exact date ordered. An additional 69 records showed that 53% of the patients were seen within seven days before or after the ordered appointment date. Ten patients were evaluated 7 to 14 days earlier and 11 patients 7 to 14 days later than the scheduled appointment date. Therefore, 72% of the patients were evaluated within one week of the ordered appointment, and 88% were seen within two weeks.

Of the 23 cases of documented OME, 70% had follow-up appointments for their initial AOM event ordered for 14 days, of which 50% showed on the actual date ordered (Figure 1). The others originally scheduled for 14 days were seen either one to seven days earlier, or one to 30 days later. Thirteen percent of the patients diagnosed with OME had follow-up appointments scheduled for 21 days, and 13% for 28 days. These patients were not evaluated on the exact date scheduled but either 10 days early or one to 16 days later then ordered. One child did not have a follow-up appointment order documented in their medical record but came in anyway and was evaluated 10 days after the diagnosis of AOM was made.

Summary

A total of 196 medical records were audited. Sixty percent of the records came from the Pediatric Clinic and 40% from the Family Practice Clinic. Sixty-nine percent of the children treated for AOM had a documented follow-up appointment to evaluate the

effectiveness of the therapy prescribed. Seventeen percent of the children were diagnosed with OME during this appointment. The first drug of choice to treat AOM was amoxicillin followed by co-trimoxazole. Family Practice Clinic providers documented pneumatic otoscopy use more frequently but overall use was significantly low. Less than 50% of the patients diagnosed with OME had documentation of risk factor counseling for AOM. Providers did not generally use decongestants, antihistamines, steroids, or referral for surgical intervention in the initial treatment of OME in accordance with the OME guideline (Stool et al., 1994a) recommendations. It was also found that most of these healthcare providers ordered follow-up intervals between 14 and 21 days instead of the 42 days recommended.

CHAPTER FIVE – SUMMARY

Conclusions and Recommendations

Concern regarding accurate diagnosis, safe and effective quality care, antibiotic resistance, and variations in the management of otitis media with effusion prior to 1994 led to the development of the OME guideline (Stool et al., 1994a). Since its development and widespread distribution in 1996 there has been limited documentation about its use and effectiveness. The purpose of this study was to examine the use of the OME guideline by providers in a United States Air Force medical treatment facility. Using a descriptive quantitative design, seven research questions were investigated during a retrospective medical chart review of 196 patients.

Of the total records requested for review 54 percent were unavailable at the time of audit. In a military environment, personnel and their families are transferred to new locations every few years. This could account for some of the unavailable records since the audit was retrospective. Others records were signed out for other medical appointments. A large number are probably taken by the parent or guardian and presumably kept at home. This might happen if the child is seen frequently at one of the other medical treatment facilities in the area, or if the parent or guardian believes the medical treatment facility might lose the record. But when the medical records are not available for the providers to review, it is difficult to provide consistent care or evaluate it.

Guideline Adherence

The first research question asked what was the adherence to the OME guideline (Stool et al., 1994a) on follow-up intervals. Before the development of the OME guideline there were no set follow-up intervals for AOM or OME. Research during guideline development highlighted the natural healing process following AOM. OME is part of this process. Dowell, Schwartz, and Phillips (1998) state approximately 70 percent of children have OME at two weeks, 50 percent at four weeks, and 20 percent at eight

weeks. Thus, the earlier a child is evaluated the greater the possibility of finding OME. This early evaluation also leads to more appointments for the child to evaluate the resolution of the OME. More appointments mean more cost to the parent in both time and money, and loss of appointments for more acutely ill patients in the medical facility. According to this study, providers were not following the recommended follow-up interval of six weeks for OME. Instead, 20 of the 23 patients with OME were evaluated before the end of four weeks. Current review of the literature supports the fact OME is expected after AOM and does not warrant antibiotic therapy or follow-up intervals shorter than six weeks unless the child is symptomatic (Dowell et al., 1998a; Paap, 1996).

In the 196 cases of AOM, 60 children had no documented follow-up appointment though the majority had one ordered. It is not known whether some of these patients were seen and the paperwork did not get into the medical record, or whether the parent or guardian failed to schedule or keep a scheduled appointment. One possibility may be the adult opted to skip the appointment if the child had been asymptomatic at the time of the scheduled follow-up. Eighteen of the patients did not have any appointment ordered by their provider in the record. Of all patients evaluated at follow-up, 72 percent were seen within one week of the appointment ordered by the provider.

The second question addressed whether antibiotics are ordered more frequently for OME if the patient is seen earlier than the recommended interval of six weeks. The majority of the patients were seen earlier than four weeks and only one of the 23 patients with OME was prescribed an antibiotic. Therefore antibiotics were not ordered more frequently when the patient was seen earlier than six weeks. This indicates consideration for the normal progression of healing after AOM and the recommended practice that antibiotics are not required. Prudent prescription of antibiotics may decrease the overuse of antibiotics, decrease side effects in children, and lessen the opportunity for antimicrobial resistance as reported by Cohen (1997) and Dowell et al. (1998a).

Every child with AOM was prescribed an antibiotic, and the overwhelming first drug of choice was amoxicillin (70%) followed by co-trimoxazole (16%). This was consistent for each provider type as well as for the Pediatric Clinic, Family Practice Clinic, and the Emergency Room. Amoxicillin remains the favored initial treatment because of its safety, effectiveness, and cost (McCracken, 1998). The current recommended dose of amoxicillin for AOM is 40 mg/kg/day. McCracken reports doses can be increased to 60 to 90 mg/kg/day in communities where penicillin-resistant pneumococci are prevalent.

The third question asked whether pneumatic otoscopes and/or tympanometers are used to diagnose OME. The results show nearly 50 percent of the providers are not documenting the use of pneumatic otoscopy or tympanometers during the follow-up appointment for AOM. The Family Practice Clinic providers documented their use 38 percent more times than the Pediatric Clinic, and medical doctors 20 percent more than advanced practice nurses. Less than 60 percent of the children diagnosed with OME had documentation of tympanic membrane mobility in their records. Instead, only subjective comments regarding fluid and bulging of the membrane were noted. Thus, guidelines recommending the use of pneumatic otoscopes and/or tympanometers in the diagnosis of OME were not being followed at this medical treatment facility.

The fourth question asked whether environmental risk factor control counseling had been documented once the diagnosis of OME was established. This counseling is one way parents can obtain the knowledge necessary to aid in decreasing the chances their child may get OME. If counseling is not documented providers can not track compliance in eliminating risk factors at future appointments. Compliance with this

recommendation was less than 50 percent. Even though the Pediatric Clinic used an ear recheck overprint listing many possible risk factors that simply had to be circled, the form was not always completed. The two risk factors identified most frequently were passive smoking and group child-care that parallels associations found in the practice guideline. Thus, the OME guideline (Stool et al., 1994a) recommendation of risk factor control counseling was not being adhered to at this medical treatment facility.

The last three questions asked whether decongestants, antihistamines, steroids, or surgery were used in the treatment of OME. The study results conclude these medications and surgery were not used in the initial treatment of OME. Therefore these cases were in compliance with OME guideline (Stool et al., 1994a).

Recommendations for Practice

Though use of a single medical treatment facility limits generalizability the data do reveal significant compliance with several steps in the medical management portion of the algorithm. The newer research being conducted on AOM and OME emphasize the need for accurate diagnosing, use of the pneumatic otoscope and/or tympanometer, use of longer follow-up intervals, and the judicious use of antibiotics. The expected healing course following AOM needs to be shown to all types of providers using methods such as continuing medical education, graduate medical education, and articles in journals. Pneumatic otoscopy must be used each and every time a child is assessed for AOM and OME. Klein (1998) and Pelton (1998) stated pneumatic otoscopy is the primary mode of diagnosis but recognize it requires considerable skill to perform. Klein (1998) stresses that "because of the importance of accurate diagnosis, the academic community should reexamine techniques for improving otoscopic skills" (p. 573).

Providers need to know that shorter follow-up intervals for AOM in asymptomatic children could result in more documented cases of OME, and that OME does not require antibiotics. Overuse of antibiotics in OME can then be avoided. These shorter intervals do cost the parent time away from work, costs for child-care of other family members, and take away appointments in the clinic that could be available for other children. In addition, the child with OME will need additional appointments to follow the resolution of the effusion. These additional appointments may be avoided if the child is seen no earlier than six weeks unless symptomatic.

Future Research

Additional studies could be done focusing on the topic of pneumatic otoscopy: where and how it is taught, and observing its use directly in the clinics. Providers could be surveyed about their knowledge regarding the OME guideline (Stool et al., 1994a) and whether it would influence their management of OME, as well as any barriers to its use. As noted in the review of the literature, research still needs to be done to measure the effectiveness of the guideline in improving quality of care, reducing health costs, and limiting malpractice liability.

Summary

Compliance with the use of treatment recommendations found in the OME guideline (Stool et al., 1994a) were noted in several key areas. Antibiotics were not used in the treatment of OME. When used for AOM the antibiotic of choice was amoxicillin which is in congruence with current literature. As recommended decongestants, antihistamines, and steroids were not used in the treatment of OME. And referral for surgery was not utilized as recommended. The study showed a lack of compliance with

the six-week follow-up interval with most children evaluated by four weeks. There was low compliance with the documentation of environmental risk control counseling and use of pneumatic otoscopy and/or tympanometry in the diagnosis of OME. Research must be conducted to investigate the barriers to compliance in the areas of follow-up intervals, risk factor control counseling, and use of pneumatic otoscopy and tympanometry in the diagnosis of otitis media with effusion.

LIST OF REFERENCES

American heritage dictionary (2nd ed.). (1985). Boston: Houghton Mifflin Company.

Berg, A. O. (1994). Middle ear effusion guideline: The co-chair's thoughts. American Family Physician, 50(5), 897-898.

Berg, A. O. (1996). Clinical practice guideline panels: Personal experience. Journal of the American Board of Family Practice, 9(5), 366-370.

Berman, S. (1996). Pediatric decision making (3rd ed.). St. Louis: Mosby.

Berman, S., & Chan, K. (1997). Ear, nose & throat. In W. W. Hay, Jr., J. R. Groothius, & A. R. Hayward, Current pediatric diagnosis & treatment (13th ed., pp. 403-412). Stamford, CT: Appleton & Lange.

Behrman, R. E., Kliegman, R. M., & Arvin, A. M. (1996). Nelson textbook of Pediatrics (15th ed.). Philadelphia: W. B. Saunders Company.

Bluestone, C. D., & Klein, J. O. (1995). Clinical practice guideline on otitis media with effusion in young children: Strengths and weaknesses. Otolaryngology, Head, and Neck Surgery, 112(4), 507-511.

Burg, F. D., Ingelfinger, J. R., Wald, E. R., & Polin, R. A. (1996). Gellis & Kagan's current pediatric therapy 15. Philadelphia: W. B. Saunders Company.

Burns, N., & Grove, S. K. (1997). The practice of nursing research: Conduct, critique, & utilization (3rd ed.). Philadelphia: W. B. Saunders Company.

Christakis, D. A. & Rivara, F. P. (1998). Pediatricians' awareness of and attitudes about four clinical practice guidelines. Pediatrics, 101(5), 825-830.

Cohen, M. L. (1997). Epidemiological factors influencing the emergence of antimicrobial resistance. In Ciba Foundation Symposium 207, Antibiotic resistance: Origins, evolution, selection and spread (pp. 223-237). New York: John Wiley & Sons.

Daly, K. (1994). Risk factors for otitis media sequelae and chronicity. Annals of Otology, Rhinology, and Laryngology, Supplement, 103, 39-42.

Dershewitz, R. A. (1988). Ambulatory pediatric care. Philadelphia: J. B. Lippincott company.

Donabedian, A. (1988). The quality of care: How can it be assessed? Journal of the American Medical Association, 260(12), 1743-1748.

Dorland's illustrated medical dictionary (25th ed.). (1974). Philadelphia: W. B. Saunders.

Dowell, S. F., Marcy, S. M., Phillips, W. R., Gerber, M. A., & Schwartz, B. (1998a). Otitis media--principles of judicious use of antimicrobial agents. Pediatrics, 101(1), 165-171.

Dowell, S. F., Marcy, S. M., Phillips, W. R., Gerber, M. A., & Schwartz, B. (1998b). Principles of judicious use of antimicrobial agents for pediatric upper respiratory tract infections. Pediatrics, 101(1), 163-165.

Dowell, S. F., Schwartz, B., & Phillips, W. R. (1998). Appropriate use of antibiotics for URIs in children: Part I. Otitis media and acute sinusitis. American Family Physician, 58(5), 1113-1118.

Eddy, D. M. (1990). Designing a practice policy: Standards, guidelines, and options. Journal of the American Medical Association, 263(22), 3077-3084.

Gates, G. A. (1996). Cost-effectiveness considerations in otitis media. Otolaryngology, Head, and Neck Surgery, 114, 525-530.

Gray, J. A. (1997). Evidence-based healthcare. New York: Churchhill Livingstone.

Haekelman, R. A., Friedman, S. B., Nelson, N. M., Seidel, H. M., & Weitzman, M. L. (1997). Primary pediatric care (3rd ed.). St. Louis: Mosby.

Homer, C. J., Grossman, R. G., & Rodman, J. (1996). Pediatric guidelines: Help or hindrance? Current Opinion in Pediatrics, 8, 430-435.

Klein, J. O. (1998). Protecting the therapeutic advantage of antimicrobial agents used for otitis media. Pediatric Infectious Disease Journal, 17(6), 571-575.

Magit, A. E. & Stool, S. E. (1993). Clinical guideline development for otitis media: A report on methodology. Otolaryngology, Head and neck Surgery, 109(3), 478-81.

Mandel, E. M., Casselbrant, M. L., Rockette, H. E., Bluestone, C. D., & Kurs-Lasky, J. (1995). Efficacy of 20- versus 10-day antimicrobial treatment for acute otitis media. Pediatric, 96(1), 5-13.

McCracken, G. H. (1998). Treatment of acute otitis media in an era of increasing microbial resistance. Pediatric Infectious Disease Journal, 17(6), 576-579.

Meritt, T. A., Palmer, D., Bergman, D. A., & Shiono, P. H. (1997). Clinical practice guidelines in pediatric and newborn medicine: Implications for their use in practice. Pediatrics, 99(1), 100-114.

Moser, R. (1994, October). Otitis media in children: Overdiagnosed and overtreated. ADVANCE for Nurse Practitioners, 21-24, 32.

Paap, C. M. (1996). Management of otitis media with effusion in young children. Annals of Pharmacotherapy, 30, 1291-1297.

Pelton, S. I. (1998). Otoscopy for the diagnosis of otitis media. Pediatric Infectious Disease Journal, 17(6), 540-543.

Poehlman, G. S. (1996). Chronic otitis media with effusion. Primary Care, 23(4), 687-699.

Sebring, R. H., & Gerrerias, C.T. (1996). The political anatomy of a guideline: A collaborative effort to develop the AHCPR-sponsored practice guideline on otitis media with effusion. Journal of Quality Improvement, 22(6), 403-411.

Shapiro, A. M. & Bluestone, C. D. (1995). Otitis media reassessed. Postgraduate Medicine, 97(5), 73-82.

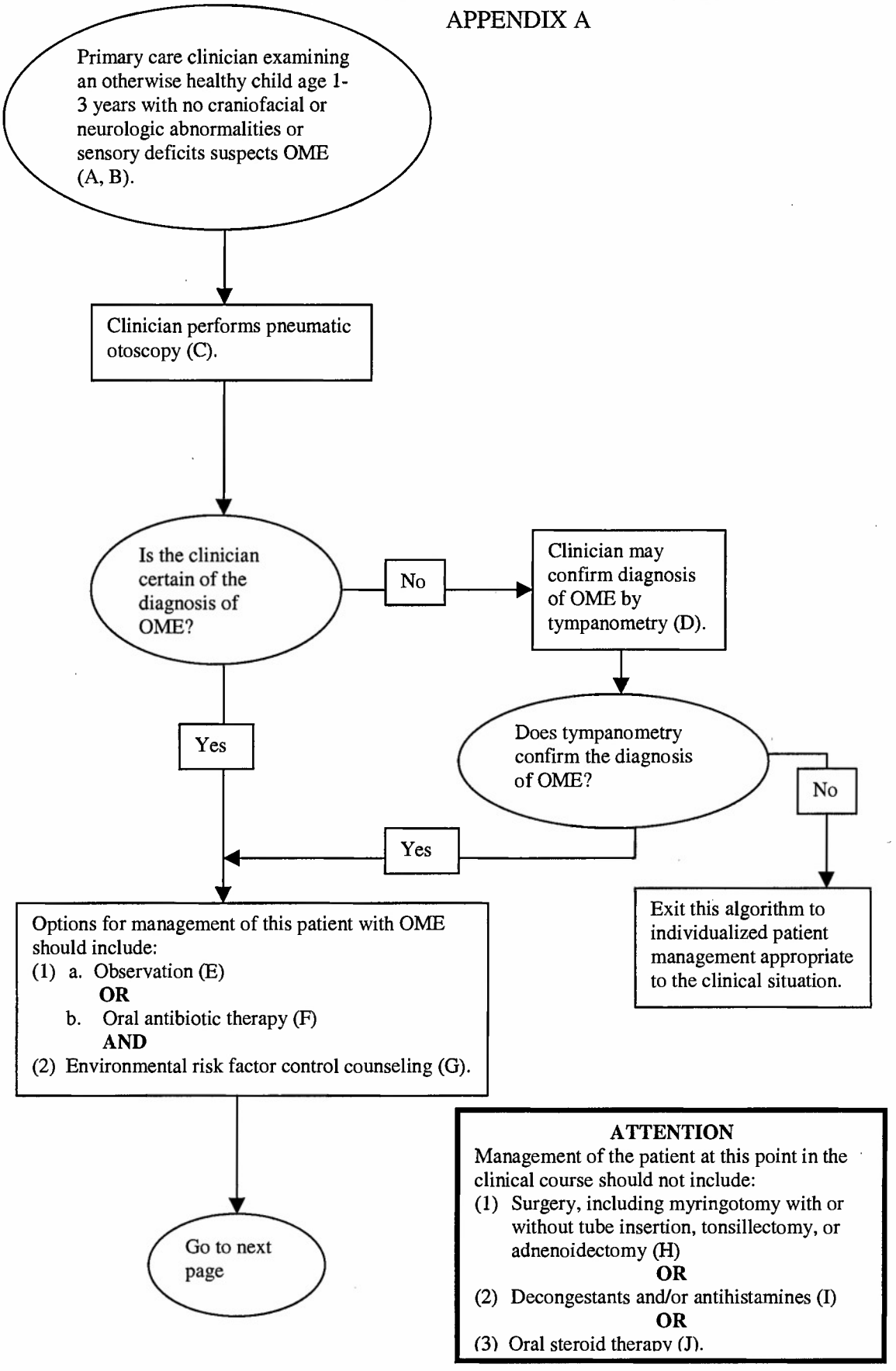
Stool, S. E., Berg, A. O., Berman, S., Carney, C. J., Cooley, J. R., Culpepper, L., Eavey, R. D., Feagans, L. V., Finitzo, T., Friedman, E. M., Goertz, J. A., Goldstein, A. J., Grundfast, K. M., Long, D. G., Macconi, L. L., Melton, L., Roberts, J. E., Sherrod, J. L., & Sisk, J. E. (1994a). Clinical practice guideline: number 12. Otitis media with effusion in young children (AHCPR Publication No. 94-0622). Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U. S. Department of Health and Human Services.

Stool, S. E., Berg, A. O., Berman, S., Carney, C. J., Cooley, J. R., Culpepper, L., Eavey, R. D., Feagans, L. V., Finitzo, T., Friedman, E. M., Goertz, J. A., Goldstein, A. J., Grundfast, K. M., Long, D. G., Macconi, L. L., Melton, L., Roberts, J. E., Sherrod, J. L., & Sisk, J. E. (1994b). Clinical practice guideline. Quick reference guide for clinicians, number 12: Managing otitis media with effusion in young children (AHCPR Publication No. 94-0623). Rockville, MD: Agency for Health Care Policy and Research, Public Health Service, U.S. Department of Health and Human Services.

U.S. Department of Health and Human Services. (1991). International classification of diseases, ninth revision, clinical modification: ICD-9-CM (4th ed.). (DHHS Publication No. 91-1260). Public Health Service, Health Care Financing Administration.

APPENDICES

OTITIS MEDIA WITH EFFUSION TREATMENT ALGORITHM
APPENDIX A



From previous page

Does the patient still have OME 6 weeks after diagnosis by pneumatic otoscopy with optional confirmation by tympanometry?

KEY

(A) Otitis media with effusion (OME) is defined as fluid in the middle ear without signs or symptoms of infection; OME is not to be confused with acute otitis media (inflammation of the middle ear with signs of infection). The guideline and this algorithm apply only to the child with OME, and assumes follow-up intervals of 6 weeks.

(B) The algorithm applies only to a child age 1-3 years with no craniofacial or neurologic abnormalities or sensory deficits (except as noted) who is healthy except for OME.

(C) The panel found some evidence that pneumatic otoscopy is more accurate than otoscopy performed without the pneumatic test of eardrum mobility.

(D) Tympanometry may be used as confirmation of pneumatic otoscopy in the diagnosis of OME. Hearing evaluation is recommended for the otherwise healthy child who has had bilateral OME for 3 months; before 3 months, hearing evaluation is a clinical option.

(E) In most cases, OME resolves spontaneously within 3 months.

(F) The antibiotic drugs studied for treatment of OME were amoxicillin, amoxicillin-clavulanate potassium, cefaclor, erythromycin, erythromycin-sulfisoxazole, sulfisoxazole, and trimethoprim-sulfamethoxazole.

(G) Exposure to cigarette smoke (passive smoking) has been shown to increase the risk of OME. For bottle-feeding versus breast-feeding and for child-care facility placement, associations were found with OME, but evidence available to the panel did not show decreased incidence of OME with breast-feeding or with removal from child-care facilities.

(H) The recommendation against tonsillectomy is based on the lack of added benefit from tonsillectomy when combined with adenoidectomy to treat OME in older children. Tonsillectomy and adenoidectomy may be appropriate for reasons other than OME.

(I) The panel found evidence that decongestants and/or antihistamines are ineffective for OME.

(J) Meta-analysis failed to show a significant benefit for steroid medications without antibiotic medications in treating OME in children.

Note. From "Guideline: Summary of Recommendations," by S. E. Stool, A. O. Berg, S. Berman, C. J. Carney, J. R. Cooley, L. Culpepper, R. D. Eavey, L. V. Feagans, T. Finitzo, E. M. Friedman, J. A. Goertz, A. J. Goldstein, K. M. Grundfast, D. G. Long, L. L. Macconi, L. Melton, J. E. Roberts, J. L. Sherrod & J. E. Sisk, 1994, Clinical practice guideline, number 12. Otitis media with effusion in young children, (AHCPR Publication No. 94-0622), p.12-15.

APPENDIX B

Otitis Media with Effusion Clinical Practice Guideline Checklist
By Major Paula Pengilly (July 1998)

Date_____

I. Inclusion Criteria Met?

A. Child between ages of 12 and 48 months?	Yes	No
B. No evidence of craniofacial, neurological, or sensory deficits?	Yes	No
C. Not on prophylactic antibiotics for acute otitis media (AOM)?	Yes	No
D. Had fewer than 3 episodes of AOM in past 6 months?	Yes	No
E. Does not have pneumatic tubes now nor in the past?	Yes	No

II. Exclusion Criteria Met?

A. Child less than 12 or more than 48 months?	Yes	No
B. Evidence of craniofacial, neurological, or sensory deficits?	Yes	No
C. Child is on prophylactic antibiotics?	Yes	No
D. Experienced $\geq$ 3 episodes of AOM in past 6 months?	Yes	No
E. Child has history of pneumatic tubes?	Yes	No

1. Age in months:_____

2. Gender: Male__ Female__

3. Clinic (Initial diagnosis AOM): Pediatric___ Family Practice___ Other____

4. Provider type: APN___ PA___ MD___ Other:_____

5. Follow-up (F/U) Intervals in Julian days:
   - 3.1 Initial AOM Appointment:_____
   - 3.2 F/U Ordered:_____
   - 3.3 Actual F/U Appointment:_____

6. Antibiotic ordered:_____
   - 1=Amoxicillin
   - 2=Amoxicillin+clavulanic acid (Augmentin)
   - 3=Azithromycin (Zithromax)
   - 4=Cefaclor (Ceclor)
   - 5=Cefixime (Suprax)
   - 6=Ceftriaxone (Rocephin)
   - 7=Erythromycin
   - 8=Erythromycin+sulfisoxazole (Pediazole)
   - 9=Sulfamethoxazole+trimethoprim (Septra)
   - 10=Other _____

7. Diagnosis on F/U:_____
   1. AOM
   2. OME
   3. Normal
   4. Other _____

8. Clinic (F/U for initial AOM): Pediatric___ Family Practice___ Other___

9. Provider type: APN___ PA___ MD___ Other___

10. Pneumatic otoscopy/and or tympanogram use documented? Yes:_____ No:_____

Continues on next page!

11. If OME:

11.1 Antibiotic ordered? Yes:____No:____

11.1.1 If yes, what?_____

1=Amoxicillin
2=Amoxicillin+clavulanic acid (Augmentin)
3=Azithromycin (Zithromax)
4=Cefaclor (Ceclor)
5=Cefixime (Suprax)
6=Ceftriaxone (Rocephin)
7=Erythromycin
8=Erythromycin+sulfisoxazole (Pediazole)
9=Sulfamethoxazole+trimethoprim (Septra)
10=Other _____

11.2 Risk factor counseling documented? Yes:_____ No:_____

11.2.1 Bottle-fed Yes No
11.2.1 Passive smoking Yes No
11.2.3 Group Child Care Yes No
11.2.4 Other:_____

11.3 Decongestant and/or antihistamine ordered? Yes:_____ No:_____

11.3.1 If yes, reason documented? Yes:_____ No:_____

11.4 Steroids ordered? Yes:_____ No:_____

11.5 Surgical intervention:

11.5.1 Recommended? Yes:_____ No:_____
11.5.2 Performed? Yes:_____ No:_____

11.6 F/U for OME recommended ?: Yes:_____ No:_____

11.6.1 If yes, when (in days)? _____

APPENDIX B-1

Checklist Code Key

1. Age: number of months (2 digits) *Missing data=0

2. Gender: 1=male 2=female

3. Clinic (Initial diagnosis): 1=Pediatric 2=Family Practice 3=Other

4. Provider type: 1=APN 2=PA 3=MD 4=Other

5. Follow-up intervals: Julian date (1-3 digits)

6. Antibiotic ordered:
   1=Amoxicillin
   2=Amoxicillin+clavulanic acid (Augmentin)
   3=Azithromycin (Zithromax)
   4=Cefaclor (Ceclor)
   5=Cefixime (Suprax)
   6=Ceftriaxone (Rocephin)
   7=Erythromycin
   8=Erythromycin+sulfisoxazole (Pediazole)
   9=Sulfamethoxazole+trimethoprim (Septra)
   10=Other _____

7. Diagnosis on follow-up:
   1=AOM
   2=OME
   3=Normal
   4=Other _____

8. Clinic (F/U for initial AOM): 1=Pediatric 2=Family Practice 3=Other

9. Provider type: 1=APN 2=PA 3=MD 4=Other

10. Pneumatic otoscopy and/or tympanogram used documented?: 1=yes 2=no

11. If OME:
    11.1 Antibiotic: 1=yes 2=no

        11.1.1 If yes, antibiotic ordered:
        1=Amoxicillin
        2=Amoxicillin+clavulanic acid (Augmentin)
        3=Azithromycin (Zithromax)
        4=Cefaclor (Ceclor)
        5=Cefixime (Suprax)
        6=Ceftriaxone (Rocephin)
        7=Erythromycin
        8=Erythromycin+sulfisoxazole (Pediazole)
        9=Sulfamethoxazole+trimethoprim (Septra)
        10=Other _____

    11.2 Risk Factor Counseling: 1=yes 2=no
        1=Bottle fed
        2=Passive smoking
        3=Group child care
        4=Other_____

    11.3 Decongestants and/or antihistamine used: 1=yes 2=no

        11.3.1 If yes, reason documented: 1=yes 2=no

    11.4 Steroid used: 1=yes 2=no

11.5 Surgical intervention:
- 11.5.1 Recommended? 1=yes 2=no
- 11.5.2 Performed? 1=yes 2=no

11.6 F/U for OME recommended: 1=yes 2=no
- 11.6.1 If yes, when (in days): 1-3 digits

UNIFORMED SERVICES UNIVERSITY OF THE HEALTH SCIENCES
4301 JONES BRIDGE ROAD
BETHESDA, MARYLAND 20814-4799
APPENDIX C

June 29, 1998

MEMORANDUM FOR MAJ PAULA T. PENGILLY, DEPARTMENT OF GRADUATE SCHOOL OF NURSING

SUBJECT: IRB Review and Approval of Protocol **T06166** for Human Subject Use

Your research protocol, entitled ***Adherence to the Otitis Media with Effusion Clinical Practice Guidelines by Providers in a USAF Medical Treatment Facility,*** was reviewed and approved for execution on **6/29/98** as an **exempt** human subject use study under the provisions of 32 CFR 219.101(b)(2). This approval will be reported to the full IRB, scheduled to meet on 7/9/98.

The IRB understands that the purpose of this study is to examine the use of the OME clinical practice guidelines by providers in a USAF medical treatment facility. The study will consist of a chart review comparing recorded treatment against a checklist of measures compiled from the practice guideline.

Please notify this office of any amendments or changes in the approved protocol that you might wish to make and of any untoward incidents that may occur in the conduct of this project. If you have any questions regarding human volunteers, please call me at 301-295-3303.

Michael J. McCreery, Ph.D.
LTC, MS, USA
Director, Research Programs and
Executive Secretary, IRB

cc: Director, Grants Administration